TMA DoD Pharmacoeconomic Center
Fort Sam Houston, TX

MTF Quarterly Webcast
September 12, 2013

Introduction

- Greetings from the PEC
- Purpose of the Quarterly MTF Webcast

- DCO Ground Rules
  - Type questions into the DCO system
  - Put on mute, not on hold
  - Contingency plan if DCO system stops working

- Final slides and Questions/Answers posted to PEC Website in a few days

Outline

- Contracting Corner
- Review of May 2013 P&T Committee Meeting
  - UF Class Reviews
  - New Drugs in Previously Reviewed Classes
  - BCF Issues
  - Utilization Management
- Overview of Aug 2013 P&T Committee Meeting
- Quick Look at Nov 2013 P&T Committee Meeting
- Questions

Contracting Corner

Jeremy Briggs

HERBIVORE

- Formulary Review
  - Basic Core Formulary
  - Extended Core Formulary
  - Non-Formulary

- Best buying practices
  National Contracts
  - Lowest Prices Alternatives

BPA Terminated

- PANCREAZE
  - Still on ECF for now

Contract Updates

Effective Date 8/26/13

Mepron 750mg/5ml Susp (Brand Only)***

NDC: 00173-0547-00
NDC: 00173-0665-18

Effective Date 8/27/13

Zidovudine

100mg caps	NDC: 52343-0044-01
300mg tabs	NDC: 52343-0045-60

Effective Date 8/28/13

Venlafaxine tabs

25mg	NDC: 42291-0892-90
37.5mg	NDC: 42291-0893-90
50mg	NDC: 42291-0894-90
75mg	NDC: 42291-0895-90
100mg	NDC: 42291-0896-90

Effective Date 8/30/13

Venlafaxine XR caps***

37.5mg	NDC: 60429-0121-30
	NDC: 60429-0121-30
75mg	NDC: 60429-0122-30
	NDC: 60429-0122-90
150mg	NDC: 60429-0123-30
	NDC: 60429-0123-90

Effective Date 9/11/13

Dificid 200mg tab (Brand Only)***

NDC: 52015-0080-01

Effective Date 9/16/13

Cefuroxime tabs***

250mg	NDC: 52343-0046-20
	NDC: 52343-0046-60
500mg	NDC: 52343-0047-20
	NDC: 52343-0047-60

***TAA Non-compliant Items

Best Generic Opportunities (G2G)

Extended Release Potassium Chloride 10mEq

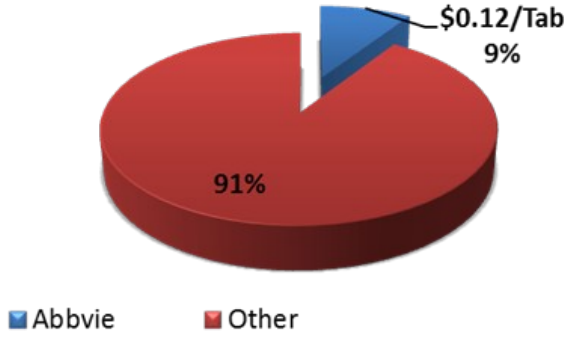
Most sites are Current Buying Upsher-Smith at $0.30/tab

Last 12 months 23M tablets

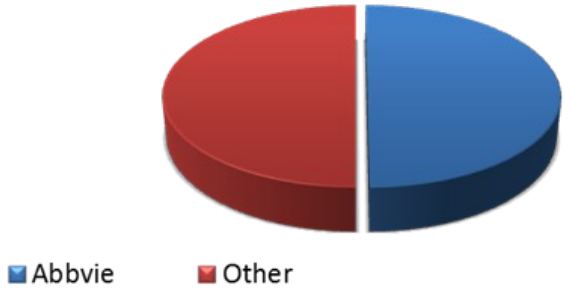
Abbvie's $0.12/tablet (FSS)

Lowest Cost Federal Price
#100 (NDC: 00074-7804-13)
#1000 (NDC: 00074-7804-19)

Current Market Picture
$5.1M Annual Spending



50% Market share Goal
$4M Annual Spending



$1M cost-avoidance over 12 months

Not all KCl is bioequivalent

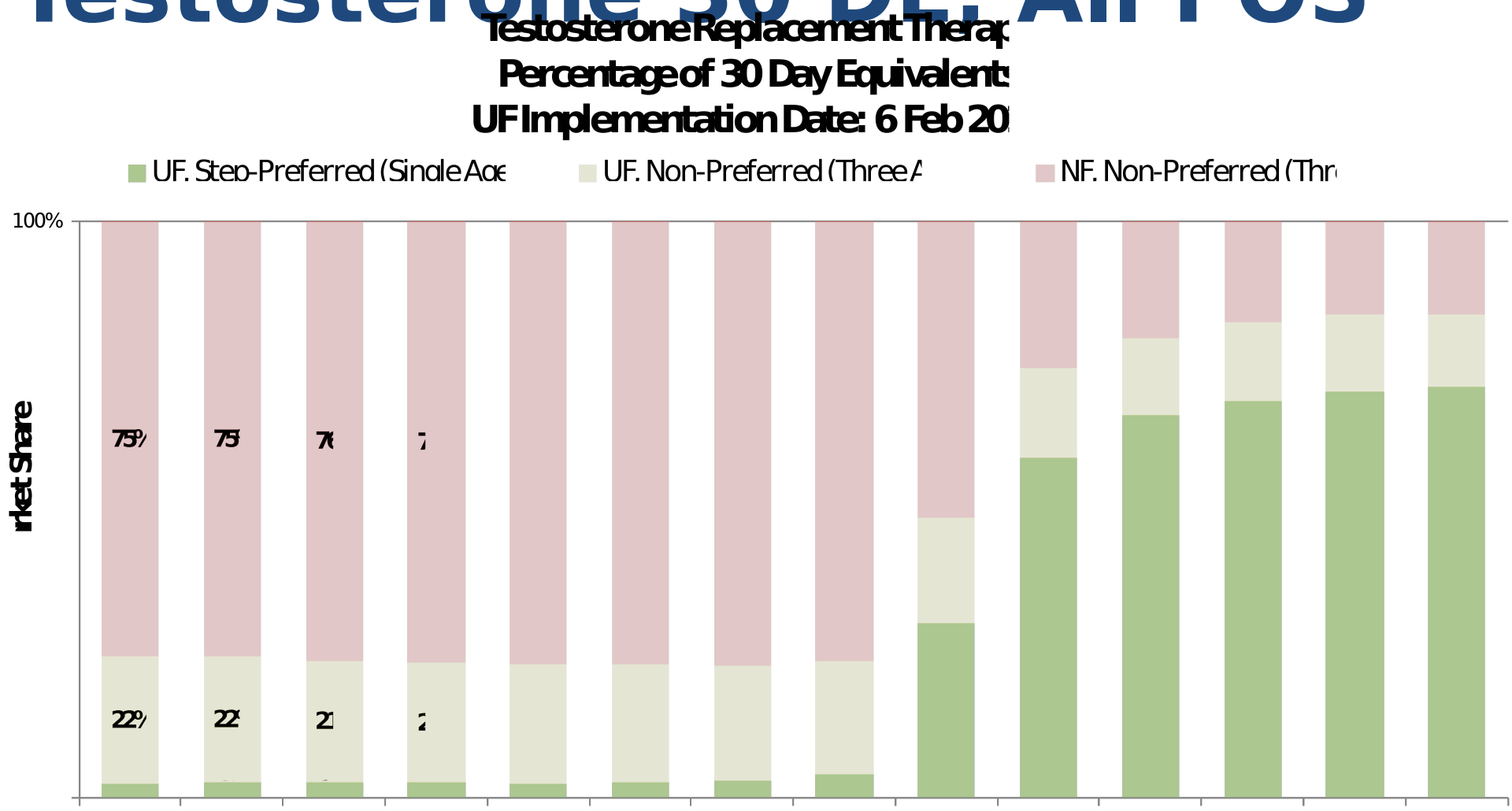
On the horizon

- National Contracts Closed
  - Escitalopram
  - Valacyclovir
  - Pioglitazone
- CPOC@dla.mil
  - TAA compliance, pharmaceutical manufacturer backorder, pharmaceutical manufacturer allocation, inclusion in the PPV program, customer provided usage, National Contract and Best pharm tool analysis

Utilization Changes After UF/PA Decisions

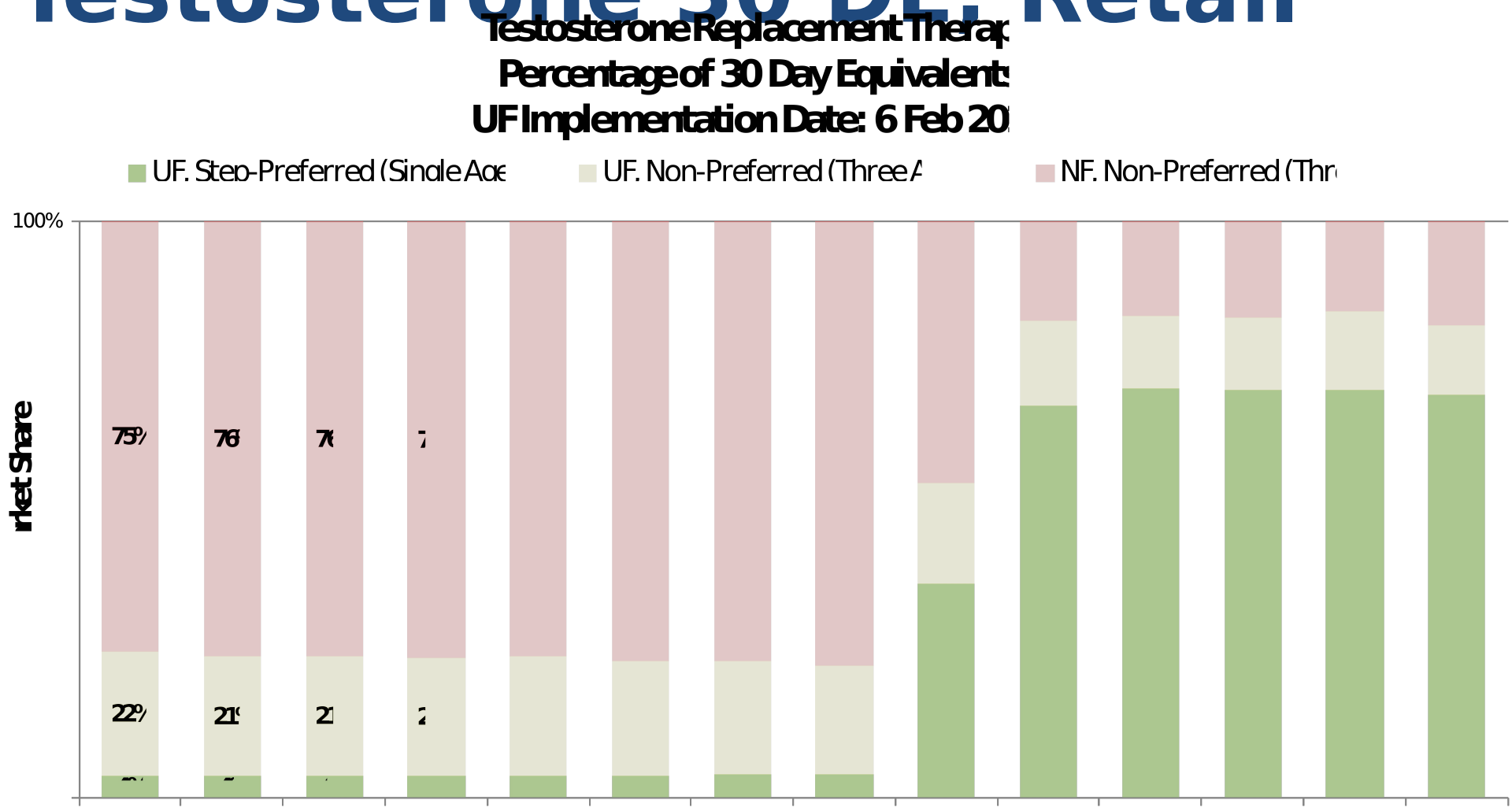
Testosterone

Testosterone 30 DE, All POS



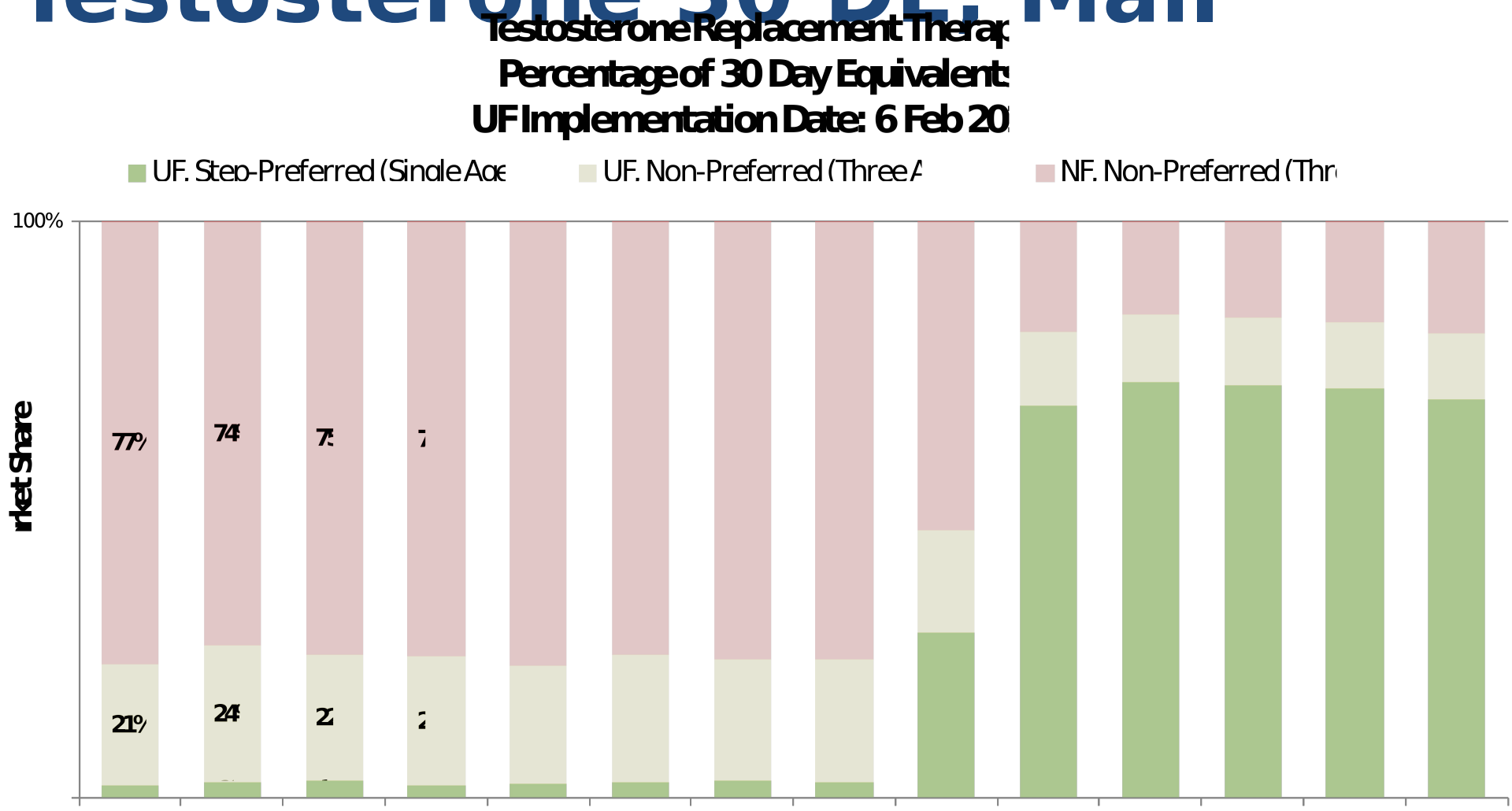
Source: PDTS, June 2012 – Jul 2013

Testosterone 30 DE, Retail



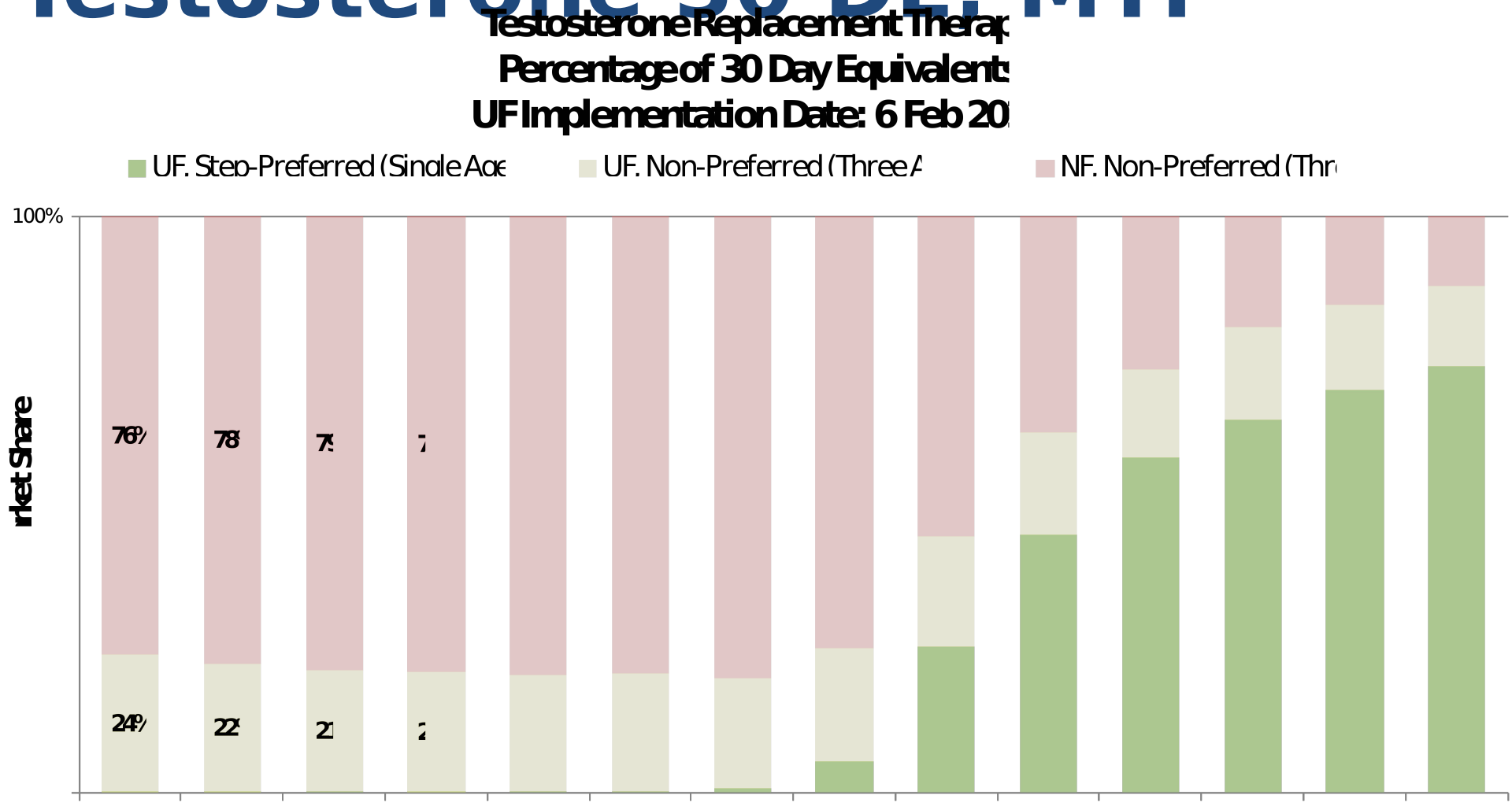
Source: PDTS, June 2012 – Jul 2013

Testosterone 30 DE, Mail



Source: PDTS, June 2012 – Jul 2013

Testosterone 30 DE, MTF



Source: PDTS, June 2012 – Jul 2013

Review of May 2013 P&T Committee Meeting

Angela Allerman, PharmD, BCPS
Clinical Pharmacist

May 2013
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Anti-Gout drugs
  - Pulmonary II drugs

- **New Drugs in Previously Reviewed Classes**
  - Non-insulin DM drugs: Canagliflozin (Invokana)

- **Utilization Management**

Uniform Formulary Class Reviews

Anti-Gout Class

Drugs in the Class

Active Ingredient	Brand (Manufacturer)	Strengths & Formulation	FDA Approval Date	Patent Expiration Date
Allopurinol	Zyloprim (generics) (Prometheus)	100mg, 300mg tablets	08/19/1966	---
Febuxostat	Uloric (Takeda)	40mg, 80mg tablets	02/13/2009	2/13/2014
Colchicine	Colcrys (Takeda)	0.6mg tablets	07/29/2009	02/10/2029
Probenecid	Probalan (Lannett)	500mg	07/29/1976	---
Colchicine/ Probenecid	Col-Probenecid (Watson)	0.5mg/500mg tablet	11/23/1976	---

- Pegloticase (Krystexxa) is a new IV biologic for chronic refractory gout; not part of pharmacy benefit; not reviewed

Overall Clinical Conclusion Efficacy

- Colchicine is a very old drug with a new extended patent life and only one available product (Colcrys)
- For an acute gout attack, colchicine is a 1st line treatment attack (along with NSAIDS) and should be initiated within the first 24 hours of symptom onset
- For chronic gout, urate lowering therapy (ULT) with allopurinol or febuxostat is recommended 1st line
  - Based on head-to-head trials febuxostat (Uloric) 40 mg and allopurinol 300 mg were equally efficacious in lowering serum Uric Acid (sUA) < 6mg/dL in one study (CONFIRMS) and febuxostat 80 mg was superior to allopurinol 300 mg in 2 studies (FACT and APEX) in lowering sUA < 6mg/dL
- Higher doses of allopurinol (doses > 300mg), although not well studied, may be required in some patients to decrease serum uric acid
- Use of colchicine for prophylaxis helps prevent gout flares during initiation of ULT, however gout flares increased when prophylaxis was discontinued in studies
- Guidelines recommend prophylaxis be given up to 6 months

Overall Clinical Conclusion Safety/Tolerability

- Colchicine is associated with a high rate of diarrhea (23%) and is contraindicated with strong 3A4 inhibitors in patients with severe renal or hepatic impairment
- Head to head studies show similar rates of ADRs with febuxostat and allopurinol
- Febuxostat has warnings regarding liver enzyme abnormalities (FDA) and increased cardiovascular events (European Medicines Agency)
  - LFTs should be tested at initiation and monitored throughout treatment and patients should be monitored for CV events
  - Febuxostat should not be used in patients with ischemic heart disease and CHF according to EMA guidelines due to increased risk of CV events
- Allopurinol must be dose adjusted in patients with renal impairment
- Allopurinol is associated with a low but serious risk of hypersensitivity reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis)

Formulary Results – Chronic Tx

- Allopurinol maintained **Basic Core Formulary (BCF)** and step-preferred
- Febuxostat (Uloric) designated Non-Formulary (NF) and non step-preferred
- All current and new users require trial of allopurinol prior to febuxostat
- Implementation: Nov 6 2013

Formulary Results – Acute TX

- Colchicine (Colcrys), probenecid, and fixed dose combo of colchicine/ probenecid are designated as UF

- All three of these products are exempt from step therapy

Pulmonary II Class

Pulmonary II Agents
Drugs in the Class

Generic Name	Brand name	Dosage Form & Strengths	Manufacturers	FDA Approval	Patent Expiration
Short acting muscarinic antagonists (SAMA)					
Ipratropium	Atrovent solution	inhalation soln 0.02% [500 mcg/2.5 mL)	generic	10/20/1995	-
	Atrovent HFA	MDI 17 mcg/actuation	Boehringer-Ingelheim	11/17/2004	2014-2020
Long acting muscarinic antagonists (LAMA)					
Tiotropium	Spiriva Handihaler	DPI; caps for oral inhalation 18 mcg/capsule	Boehringer-Ingelheim	1/30/2004	2018-2021
Aclidinium	Tudorza Pressair	DPI 400 mcg/actuation	Forest	7/23/2012	2016-2027
Beta-Adrenergic Agonist and Anticholinergics Combination					
Ipratropium and albuterol	Combivent	MDI Ipratropium 18 mcg and albuterol* 90 mcg/actuation	Boehringer-Ingelheim	10/24/1996	Last sale date: 12/31/2013
	DuoNeb	inhalation soln Ipratropium 0.5 mg and albuterol* 2.5 mg/3 mL	generic	3/21/2001	-
	Combivent Respimat	Soft mist inhaler ipratropium 20 mcg and albuterol* 100 mcg/actuation	Boehringer-Ingelheim	10/07/2011	2013- 2020
Phosphodiesterase-4 inhibitor					
Roflumilast	Daliresp	500 mcg/tab	Forest	2/ 28/2011	1/27/2015

*albuterol base; MDI=metered-dose inhaler; DPI=dry powder

Overall Clinical Conclusion

- **Tiotropium (Spiriva)**
  - First LAMA on the market; long history of use
  - Once daily treatment
  - Statistically significant improvement in trough FEV_1 compared to placebo
  - Associated with a significant decrease in the risk for a COPD exacerbation
    - Reduction in exacerbation placebo adjusted; UPLIFT – 14% and VA Trials – 19%
    - Cochrane 2012; NNT of COPD exacerbation was 16 over one year
  - Tiotropium reduced the proportion of patients hospitalized for COPD exacerbations
  - Asthma
    - Tiotropium was associated with reductions in steroid requirements as well as improvement in the PEF and FEV_1
  - Previous concerns of CV safety have not been confirmed with available data
  - Usual anticholinergic concerns exist with LAMA/SAMA drugs

Overall Clinical Conclusion

- **Aclidinium (Tudorza)**
  - 2nd LAMA on the market
  - BID dosing
  - Statistically significant improvement in trough FEV_1 compared to placebo (3 trials)
  - Associated with a significant decrease in the risk for a COPD exacerbation, compared to placebo (2 trials)
  - ADRs are minimal; primarily anticholinergic events reported. There is limited data with the 400 mcg approved dose. FDA is requiring a CV safety study.
  - Longer duration and larger comparative trials are needed to determine the drug's place in therapy.

Overall Clinical Conclusion

- **Roflumilast (Daliresp)**
  - First selective inhibitor of phosphodiesterase type 4 (PDE-4) in U.S.
  - Available in oral formulation
  - FDA indication is limited to the reduction in the incidence of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations
  - Roflumilast should not be used to treat acute bronchospasm
  - Associated with modest improvement in FEV_1 from baseline
    - MD in FEV_1 54.32 mL is below the Minimally Clinically Important Difference (100 mL)
    - Largest increases in FEV_1 observed when used in combination with the long acting bronchodilators
  - Modest improvement in FVC, from baseline, reported in 12 trials
  - PDE4 inhibitors statistically significantly reduction COPD exacerbations by approximately 25%
  - In trials used to gain FDA approval, concerns of psychiatric events (including suicide), weight loss, GI upset, and nasal tumors were identified. However, the FDA did not require additional prospective safety studies. REMS is not required

Overall Clinical Conclusion

- **Combivent Respimat**
  - Propellant-free inhaler to replace Combivent CFC inhaler
  - Combivent Respimat 20/100 met predefined goals
    - Non-inferior to Combivent MDI
    - Superior to ipratropium Respimat at 0 to 4 hours
    - Non-inferior to ipratropium Respimat at 4 to 6 hours
  - Some older patients or patients with hand joint problems may require assistance for the initial assembly of the inhaler and cartridge
  - Safety profile is similar to Combivent CFC/MDI
  - Usual anticholinergic concerns exist with LAMA/SAMA drugs

Formulary Status

Generic Name	Brand name	Dosage Form & Strengths	Formulary Status
Short acting muscarinic antagonists (SAMA)			
Ipratropium	Atrovent solution	inhalation soln 0.02% [500 mcg/2.5 mL)	UF
	Atrovent HFA	MDI: 17 mcg/actuation	**BCF**
Long acting muscarinic antagonists (LAMA)			
Tiotropium	Spiriva Handihaler	DPI: caps for oral inhalation 18 mcg/capsule	**BCF**
Aclidinium	Tudorza Pressair	DPI: 400 mcg/actuation	UF
Beta-Adrenergic Agonist and Anticholinergics Combination			
Ipratropium and albuterol	Combivent	MDI: Ipratropium 18 mcg and albuterol* 90 mcg/ inhalation	UF till 12/31/2013
	DuoNeb	inhalation soln: Ipratropium 0.5 mg and albuterol* 2.5 mg/3 mL	**BCF**
	Combivent Respimat	Soft mist inhaler: ipratropium 20 mcg and albuterol* 100 mcg/inhalation	UF
Phosphodiesterase-4 inhibitor (PDE-4 inh)			
Roflumilast	Daliresp	Tablet, oral: 500 mcg/tab	UF

*albuterol base; MDI=metered-dose inhaler; DPI=dry powder inhaler

New Drugs in Previously Reviewed Classes

Canagliflozin

- Brand: Invokana
- Manufacturer: Janssen Pharmaceuticals
- Class: SGLT2 Inhibitor
- FDA approval date: March 29, 2013
- Strengths: 100mg and 300mg
- Dosage Form: oral tablets
- Dosing: 100mg daily, may increase to 300mg daily

Canagliflozin

- Canagliflozin is a new DM drug that functions as an SGLT2 inhibitor
  - It's MOA is to
    - ↓ reabsorption of filtered glucose
    - ↓ RT_G (renal threshold for glucose)
    - ↑ UGE (urinary glucose excretion)
- SGLT2 inhibitors are a new subclass of the non-insulin DM drugs class
- Efficacy is limited to 8 clinical trials, showing moderate decreases in A1c from baseline ranging from 0.63% (with insulin) to 1.11% (monotherapy treatment naïve)
- Safety concerns include
  - Hypotension, impaired renal function, ↑ K+, ↓ Mg, ↑ PO_4, ↑ LDL, ↓ Hgb, hypoglycemia, UTIs (male and female), genital mycotic infections, and increased LDL
  - There is only limited safety information available
- There are no long-term outcomes trials available

Formulary Status

- Recommendation
  - Non-formulary status – implementation: Sept 25, 2013
- Clinical Justification
  - Modest A1c benefits
  - Significant safety concerns
  - No outcomes data
  - Not addressed in current DM clinical practice guidelines
  - Current cost is more expensive than UF alternatives, including metformin, sulfonylureas, thiazolidinediones, and dipeptidyl peptidase-4 inhibitors
- Prior Authorization also applies
  - Requires a trial of metformin, sulfonylurea, or a DPP-4 inhibitor in all new and current users of canigliflozin (Invokana)

BCF Issues

Emergency Contraceptives

- Remove levonorgestrel 0.75mg (Next Choice) from the BCF
- No emergency contraceptive is designated as BCF. Plan B One Step now OTC for all ages.
- Dr Woodson approved, but modified the language of the minutes to state that MTFs shall carry Plan B One Step and provide it at no cost

Mesalamine (Asacol)

- Mesalamine (Asacol) was discontinued by the manufacturer and supplies have been depleted
- Committee recommended to remove Asacol for the BCF
- Other mesalamine delayed release tablets are on the UF
- No replacement BCF agent selected until GI-1 class can be re-reviewed

Utilization Management (UM)

UM actions

- Generic pantoprazole is now cost effective and has been designated as step-preferred
  - Pantoprazole, omeprazole, Nexium preferred PPIs
  - Must try one of these 3 before other PPIs
- Icosapent ethyl (Vascepa) now has manual PA criteria which limits use of product to FDA-approved indications
- Abiratorone (Zytiga) PA criteria was updated to reflect new indication for medication
  - Product now labeled to treat metastatic castration-resistant prostate cancer on concomitant prednisone

Overview of August 2013 P&T Committee Meeting

August 2013
DoD P&T Committee Meeting

- **Uniform Formulary Class Reviews**
  - Self-Monitoring Blood Glucose System Test Strips
  - Topical Steroids

- Prior Authorization
  - Acthar Gel
  - Doxylamine/pyridoxine (Diclegis)

Quick Look at Nov 2013 P&T Committee Meeting

Nov 2013
DoD P&T Committee Meeting

- Uniform Formulary Class Reviews
  - Antilipidemic-1s
  - Short Acting Beta Agonists
  - Inhaled Corticosteroids/Long Acting Beta Agonists
  - Benign Prostatic Hyperplasia Agents

- Designated Newly Approved Drugs
  - Effervescent alendronate (Binosto)
  - DPP-4 inhibitor: Alogliptin (Kazano), with metformin (Nesina), with pioglitazone (Oseni)

Other Issues

Questions?

Miscellaneous items

- PEC website
  - Email questions to usarmy.jbsa.medcom-ameddcs.mbx.pecweb@mail.mi
  - For other questions, formulary clarification, etc usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil
- Next webcast will be held on Dec 12th 2013 at 0900 and 1700 EST

Webcast Evaluations

- Please assist us in improving the webcast presentations by completing an anonymous, 5-question survey
- Link: http://www.zoomerang.com/Survey/WEB22CTVSNWFRP
- Thank you!

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  - usarmy.jbsa.medcom-ameddcs.list.pecuf2@mail.mil
    - For other questions, formulary clarification, etc